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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,579	10/27/2000	A. John Bramley	2001796-0006	5413

7590 04/29/2003

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/698,579

Applicant(s)

Bramley et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Apr 21, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other: _____

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ADVISORY ACTION

Applicant's response filed April 21, 2003 (Paper Number 14) has been received and entered. Consequently, claims 1-26 remain pending in the instant application, of which claims 4-26 have been withdrawn from further consideration as drawn to a non-elected invention in Paper Number 8, received May 28, 2002.

Claim Rejections - 35 USC § 102

1. The rejection of claims 1-3 under 35 U.S.C. 102(e) as being clearly anticipated by Brockaert et al is maintained.

Applicant's are asserting that claim 1 recites a nucleic acid comprising a modified gene encoding a non-mammalian anti-microbial protein, the gene including a sequence that codes for an amino acid sequence that is *identical* to the anti-microbial protein produced by the natural host except that the coding sequence includes one or more alterations that *disrupt one or more mammalian post-translational processing events* so that the non-mammalian protein is produced and secreted by mammalian cells in its active form. Applicant's further assert that what constitutes as a post-translational processing event is described at page 14, lines 5-9. Applicant's further assert that a specific glycosylation site is described at page 14, line 17 to page 15, line 6. Applicant's further assert that the asparagine to arginine mutation at position 27 of the mature

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protein has nothing to do with disrupting a post-translational modification site, and that Brockaert does not mention anything about disrupting post-translational processing events.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of the disclosure of Brockaert et al.

First, Applicant assert that claim 1 recites a nucleic acid comprising a modified gene encoding a non-mammalian anti-microbial protein, the gene including a sequence that codes for an amino acid sequence that is *identical* to the anti-microbial protein produced by the natural host except that the coding sequence includes one or more alterations that *disrupt one or more mammalian post-translational processing events* so that the non-mammalian protein is produced and secreted by mammalian cells in its active form. However, the nucleic acid disclosed by Brockaert et al is identical to the natural protein except for the mutation of asparagine to arginine. This mutation metes the claim limitation of "one or more alterations that disrupt one or more mammalian post-translational processing events."

Second, Applicants further assert that what constitutes as a post-translational processing event is described at page 14, lines 5-9 and that a specific glycosylation site is described at page 14, line 17 to page 15, line 6. However, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, while Applicants have

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described a specific glycosylation site at pages 14-15, the claims are not limited to a “particular” glycosylation site, and therefore is not germane to the rejected claims.

Finally, Applicants assert that the asparagine to arginine mutation at position 27 of the mature protein, as disclosed by Brockaert et al, has nothing to do with disrupting a post-translational modification site, and that Brockaert does not mention anything about disrupting post-translational processing events. However, asparagine is an amino acid which can be glycosylated (post-translationally) by mammals. Brockaert et al therefore, by deleting the potential glycosylation site of asparagine, created a mutation which “disrupts one or more mammalian post-translational processing events.” Applicants further assert that Brockaert et al does not mention disrupting post-translational processing systems. However, Applicant’s are again directed back to the claims. The claims are drawn to nucleic acid molecules, the intended use of the molecule does not carry any patentable weight.

The claims are drawn to a nucleic acid comprising a modified gene encoding a non-mammalian anti-microbial protein, the gene including a sequence that codes for an amino acid sequence that is identical to the anti-microbial protein produced by the natural host except that the coding sequence includes one or more alterations that disrupt one or more mammalian post-translational processing events so that the non-mammalian protein is produced and secreted by mammalian cells in its active form.

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Brockaert et al (U.S. Patent Number 5,824,869) disclose of DNA encoding anti-microbial proteins isolated from seeds. Brockaert et al further disclose of creating mutations to the coding region of the gene including a mutation of asparagine to arginine. (See column 2 and Example 22). Brockaert et al further disclose that the proteins can be expressed in suitable cells, including mammalian cells. (See column 4).

In view that Brockaert et al disclose of a nucleic acid encoding a non-mammalian anti-microbial protein, which has been altered by one or more alterations compared to the natural host, and that the protein was secreted in its active form, the DNA disclosed by Brockaert et al is deemed to anticipated the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

April 28, 2003